K122515

SEP 11 2012

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 17, 2012
Submitter:	GE Healthcare 9900 Innovation Dr. Wauwatosa, WI 53226
Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. Phone: 414-721-4214 Fax: 414-918-8275
Device: Trade Name:	C2-9-D Ultrasound Transducer
Common/Usual Name:	C2-9-D Ultrasound Transducer
Classification Names:	Diagnostic Ultrasound Transducer, 21 CFR 892.1570
Product Code:	90-ITX
Predicate Device(s):	K110943 GE LOGIQ E9 Diagnostic Ultrasound System including C1-5-D transducer
Device Description:	The C2-9-D is an ultrasound-imaging device that is attached to a GE ultrasound imaging system and used for diagnostic imaging. This device does not directly control energy delivered to the patient nor contain any software. The C2-9-D is primarily an abdominal transducer and its primary applications are pediatrics and obstetrics, however it may also be used for other applications as described in the indications for use.
Intended Use:	The device is intended for use by a qualified physician for use with GE Diagnostic Ultrasound Systems for ultrasound evaluation of Fetal; Abdominal; Pediatric; Peripheral Vascular; Urology (including prostate).
Technology:	The C2-9-D Transducer employs the same fundamental scientific technology as its predicate device(s).
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The C2-9-D Transducer and its applications comply

with voluntary standards:

1. IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2,Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment when connected to a GE Ultrasound System
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment when connected to a GE Ultrasound System
7. ISO14971, Application of risk management to medical devices

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, C2-9-D Transducer, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the C2-9-D Transducer to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 11 2012

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K122515
Trade/Device Name: C2-9-D Diagnostic Ultrasound Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: August 17, 2012
Received: August 17, 2012

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the C2-9-D Diagnostic Ultrasound Transducer, as described in your premarket notification:

Transducer Model Number

GE C2-9-D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua C. Nipper at (301) 796-6524.

Sincerely Yours,

for

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: C2-9-D Diagnostic Ultrasound Transducer

Indications for Use:

The device is intended for use by a qualified physician for use with GE Diagnostic Ultrasound Systems for ultrasound evaluation of Fetal; Abdominal; Pediatric; Peripheral Vascular; Urology (including prostate).

Prescription Use_X___ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122515

Diagnostic Ultrasound Indications for Use Form
GE C2-9-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application / Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse[9]	Other [Notes]
Ophthalmic											
Fetal/Obstetrics[7]	N	N	N	N	N	N	N	N	N	N	[5,6,9]
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	[3,5,6,9]
Pediatric	N	N	N	N	N	N	N	N	N	N	[3,5,6,9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N	N	N	N	N	N	N	N	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[9] Volume navigation
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
OIVD

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